IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.*,

Plaintiffs,

v.

DAVID YOST, in his official capacity as Attorney General of the State of Ohio, *et al.*,

Defendants.

Case No. 1:19-cv-00118

JUDGE MICHAEL R. BARRETT

PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION AND/OR A TEMPORARY RESTRAINING ORDER

INTRODUCTION

Controlling Supreme Court and Sixth Circuit law bars the State from banning D&Es,[1] the most common abortion method after approximately 15 weeks of pregnancy. Against this backdrop, the State makes two dispositive concessions: first, it concedes that D&Es "account for nearly all second trimester abortions in Ohio," and, second, that the Act on its face criminalizes the performance of D&Es unless fetal demise has already occurred. ECF No. 25 (Opp.) 5 n.11. Consistent with *every* court to have considered the validity of a similar statute, these facts alone render the Act unconstitutional. The State's attempt to distort and mischaracterize controlling precedent does not change this result. Further, its contention that physicians can comply with the Act by using "alternative methods" to ensure fetal demise before every D&E has been rejected by every court to consider the same argument and is contradicted by clear record evidence demonstrating that these methods are unsafe, unavailable, or unreliable. Plaintiffs are thus overwhelmingly likely to succeed on the merits—the only seriously contested issue on their application for a preliminary injunction. The Court should enjoin the Act.

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. Under Controlling Precedent, The Act Is Unconstitutional

The State ignores controlling precedent, including Supreme Court and post-*Gonzales v. Carhart* Sixth Circuit caselaw directly on point. Four decades of precedent establish that it is unconstitutional to ban the most common method of abortion. *See* 550 U.S. 124 (2007); *Stenberg v. Carhart*, 530 U.S. 914 (2000); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52 (1976). Sixth Circuit precedent confirms what this line of cases makes clear: a statute

[1] Plaintiffs incorporate all abbreviations and definitions used in their opening brief, ECF No. 4.

that prohibits D&E "create[s] an unconstitutional undue burden on a woman's right to terminate her pregnancy." *Northland Family Planning Clinical, Inc. v. Cox*, 487 F.3d 323, 339 (6th Cir. 2007) (that principle "has in no way been undermined" by the Court's decision in *Gonzales*). In addition, *every other court* to consider statutes nearly identical to the Act has applied that same precedent and found them unconstitutional.[2]

The State contends that neither *Stenberg* nor *Northland Family Planning* provides "much, if any, guidance" because they did not consider alternatives to a banned procedure. Opp. 26. That is simply incorrect. In *Stenberg*, the Supreme Court invalidated a statute that (like the Act) banned D&Es performed on a "living unborn child" (*i.e.*, D&E without demise) even as it acknowledged that some physicians performed demise before D&Es using digoxin and potassium chloride—the "alternatives" the State claims save the statute here. 530 U.S. at 925, 945-46. And in *Northland Family Planning*, the Sixth Circuit considered and rejected alternatives to D&E as infeasible: induction abortions entailed "more pain … expense[, and] risk of infection," 487 F.3d at 329, and removal of the uterus was "more invasive and dangerous" than D&E, *id.* at 330; *see also Danforth*, 428 U.S. at 76 (noting alternative methods of hysterotomy and hysterectomy). Like the statutes invalidated in this line of cases, the Act bans what is undisputedly the most common abortion method after approximately 15 weeks of pregnancy, *see* Opp. 5 n.11 & 12, leaving only less safe alternatives to D&E, *see* Opp. 5 n.11 (conceding induction abortion is riskier than D&E). Such a statute unduly burdens the right to a previability abortion.

---

[2] *See, e.g.*, *West. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018), *petition for cert. filed*, No. 18-837 (U.S. Dec. 20, 2018); *Whole Women's Health v. Paxton*, 280 F. Supp. 3d 938 (W.D. Tex. 2017), *appeal filed*, No. 17-51060 (5th Cir. Dec. 1, 2017).

The State invites the Court to ignore this dispositive principle, asserting that physicians could comply with the Act by successfully causing fetal demise prior to performing every D&E. *See, e.g.*, Opp. 13-14, 26. But under controlling precedent, an exception for when fetal demise has been achieved is legally irrelevant. Indeed, the statute in *Stenberg* criminalized the performance of a D&E on "a living unborn child," but it did not apply if fetal demise had already occurred. 530 U.S. at 922 (citation omitted). The Supreme Court was well aware of fetal demise procedures that—by the State's logic—would have provided physicians an alternative means of performing D&Es in compliance with the D&E ban at issue. *Id.* at 945. Despite the existence of demise procedures, the Supreme Court nevertheless invalidated the D&E ban. *See id.* at 945-46. If available fetal demise procedures were not sufficient to uphold the statute in *Stenberg*, such demise procedures cannot save the Act at issue here.[3] Moreover, as discussed in Section I.B.2, *infra*, fetal demise methods do not provide a feasible way of complying with the statute. Nor does the State's suggestion that there is medical uncertainty regarding the safety of its proposed demise methods carry the day, as discussed in Section I.B.2.a, *infra*.

B. The Act Imposes An Undue Burden On Patients Seeking D&E Procedures

Under the undue burden test set forth in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), and reaffirmed in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), courts assessing an abortion restriction must balance the "burdens a law imposes on abortion access together with the benefits those laws confer." 136 S. Ct. at 2309 (citing *Casey*, 505 U.S. at 887-98). The Act forces patients seeking D&E to endure

[3] Even the cases the State contends are controlling, *Gonzales* and *Women's Medical Prof'l Corp. v. Taft*, 353 F.3d 436 (6th Cir. 2003), which considered statutes banning dilation and extraction ("D&X") abortions, do not aid the State. These bans were upheld only and precisely because the statutes explicitly exempted D&Es. *Gonzales*, 550 U.S. at 164; *Women's Med. Prof.*, 353 F.3d at 453. By contrast, the Act specifically removes the exception for standard D&Es that was contained in Ohio's previous ban on D&X.

significant burdens while failing to advance the State's purported interests. Because the Act's burdens plainly outweigh any benefits, it imposes an undue burden and is unconstitutional.

1. The undue burden test applies

The Supreme Court's undue burden cases apply a single standard to abortion restrictions regardless of the State's purported interest. *See Casey*, 505 U.S. at 877 ("[A] statute which, while furthering the interest in potential life *or some other valid state interest*, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." (emphasis added)).[4] *Casey* itself applied that standard to restrictions that purported to protect potential life, *id.* at 887-98—the same interest the State asserts here, *see* Opp. 19-20. The Supreme Court reaffirmed the point in *Whole Woman's Health*, explaining that "[t]he rule announced in *Casey* … requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." 136 S. Ct. at 2309 (explicitly noting that "*Casey* … perform[ed] this balancing" as to a restriction related to an interest in potential life).

The State does not even attempt to engage in the required balancing analysis. Instead, it contends that "the undue-burden test works a bit differently" where the State asserts an interest in "respect for life" rather than patient health. Opp. 19. Under the State's re-worked undue burden test, rational basis review applies—*i.e.*, the Court would simply defer to the State's claims that the law furthers its asserted interests—and the law imposes an unconstitutional undue burden if it subjects women to significant health risks. But the State is merely arguing for the same test the Fifth Circuit applied in *Whole Woman's Health*, which the Supreme Court

[4] Indeed, it would make little sense for courts to apply entirely different standards depending on what interest a state invoked, as states could simply claim a particular interest in order to have the law reviewed under a more lenient standard.

explicitly rejected. *See* 136 S. Ct. at 2309 (holding that it "is wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue"). Indeed, the argument that the undue burden test varies depending on the State's asserted interests has been consistently rejected by lower courts as a "work of fiction" that is "unsupported" by Supreme Court precedent. *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 231 F. Supp. 3d 218, 228 (W.D. Tex. 2017).[5] Even in *Gonzales*, which the State contends supports the application of a rational basis test, the Supreme Court did not apply the State's proposed standard. Rather, it applied *Casey's* undue burden standard in assessing a statute purporting to advance an interest in potential life. *See* 550 U.S. at 156 ("[T]he Act … would be unconstitutional 'if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.'" (quoting *Casey*, 505 U.S. at 878)); *id.* at 158-63 (assessing the statute's asserted benefit, respect for life, together with its burdens based on record evidence).

2. The Act imposes an undue burden because demise procedures do not provide a safe, reliable, or available alternative

The State contends that the Act does not impose an undue burden by pointing to three fetal demise procedures that it claims provide "safe, effective, and available" alternatives to D&E without demise. Opp. 21.[6] Yet the evidence makes plain that these demise procedures add additional risk for every patient beyond the risks associated with the D&E itself, are unavailable

[5] *See also Hopkins v. Jegley*, 267 F. Supp. 3d 1024, 1055 1069 (E.D. Ark. 2017), *appeal filed*, No. 17-2879 (8th Cir. Aug. 28, 2017); *Planned Parenthood of Ind. & Ky. Inc. v. Comm'r*, 273 F. Supp. 3d 1013, 1020 (S.D. Ind. 2017), *aff'd* 896 F.3d 809 (7th Cir. 2018).

[6] The State relies heavily on the declaration of its expert, Dr. Michael Valley, for the arguments made in this section and throughout their brief. Dr. Valley is a signatory to the September 2012 Dublin Declaration on Maternal Healthcare, which states unequivocally that abortion is never medically necessary, even to save the life of a pregnant woman. *See* https://betterthanabortion.wordpress.com/tag/doctors-against-abortion.

or ineffective for a significant number of patients, and are unstudied or unsafe to attempt for others—including all patients below 18 weeks LMP (when the majority of D&Es occur). Even the State acknowledges, as it must, that the procedures do not always meet its own criteria. *See id.* at 8, 22 (acknowledging digoxin may fail); *id.* at 21 (acknowledging risks associated with digoxin); *id.* at 7 (acknowledging that digoxin is unavailable before 18 weeks LMP). Critically, physicians cannot know ahead of time whether a demise procedure will work and therefore cannot guarantee demise without jeopardizing patient health. Declaration of Lisa Keder, M.D., M.P.H. (Keder Decl.) ¶¶ 34, 46. Thus, under the Act, *every individual* who seeks a D&E faces the possibility that a mandated demise procedure may fail, forcing her physician to choose between acting in her best interest by completing the procedure (but violating the law)or subjecting her to a second and experimental demise attempt. None of the demise methods proposed by the State provides a safe, reliable, and available means of performing D&E in compliance with the Act.

a. Digoxin is not a feasible means of complying with the Act

Digoxin injections used to attempt demise do not save the Act. *First*, as the State acknowledges, digoxin injections carry a risk of "infection, extramural deliveries, and pain" for all patients. Opp. 21.[7] They are also contraindicated for patients with certain cardiac and other health conditions. *See* Keder Decl. ¶ 36.

[7] The State argues that the risks associated with digoxin are "also associated with all second-trimester abortions" and thus do not rise to the level of an undue burden. Opp. 21-22. That digoxin may entail the same *type* of risks as the abortion itself does not lessen the fact that the additional injection increases the *degree* of risk. Rebuttal Declaration of Lisa Keder, M.D., M.P.H. (2d Keder Decl.) ¶ 22. It is nonsensical to argue that an increased degree of risk does not impose a burden so long as the risk is of the same type, and no court has ever held such. As Dr. Keder explains, the injection generates additional risks of infection, injury to the bladder or vessels, and membrane rupture. *Id*. Digoxin also poses a host of *different* risks due to the potential for adverse reactions. *Id.*

Second, digoxin injections are not always effective, as failure to cause demise occurs in up to 10% of cases. In the event of a failure, the physician would face an impossible choice: (1) commit a felony by completing the procedure (without demise) for the sake of the patient's health and safety, (2) put the patient at risk by performing a second, experimental demise attempt, *see id*. ¶ 35 (second injection is not feasible, as no study has established the risks, appropriate dosage, or time to fetal demise for a second digoxin injection), or (3) let the patient's health deteriorate so far as to trigger the Act's extremely narrow health exception. The State acknowledges that digoxin may fail (and thus that this scenario might materialize), Opp. 7, but fails entirely to reckon with the implications for the feasibility of digoxin injections.

Third, while the State attempts to paint digoxin injections as routine in Ohio, they are not, in fact, provided or available for the *significant majority* of individuals receiving D&Es. Most D&Es in Ohio occur before 18 weeks LMP. Second Declaration of Sharon A. Liner, M.D. (2d Liner Decl.) ¶ 3 (85% of D&Es at PPSWO occur before 18 weeks LMP); Second Declaration of W.M. Martin Haskell, M.D. (2d Haskell Decl.) ¶ 3 (53% of D&Es at Women's Med occur before 18 weeks LMP); Declaration of Adarsh Krishen, M.D., M.M.M. (Krishen Decl.) ¶ 6 (70% of D&Es at PPGOH occur before 18 weeks LMP). None of Plaintiffs' physicians attempts demise using digoxin before 18 weeks LMP—and for good reason. Digoxin is virtually unstudied at that stage, meaning it would amount to an experimental treatment that has not been proven to be either safe or effective. Rebuttal Declaration of Lisa Keder, M.D., M.P.H. (2d Keder Decl.) ¶ 13; *see Danforth*, 428 U.S. at 78-79 & n.12 (alternative abortion method was "not available" because it had been used only on an experimental basis until two years earlier). Further, the potential risks of using digoxin may be higher at this stage than later in pregnancy. 2d Keder Decl. ¶ 15 (dismissing State expert Dr. Valley's claim that there is "no difference between a fetus

that is 15 to 16 weeks LMP as compared to 17 weeks," Declaration of Michael T. Valley, M.D. (Valley Decl. ¶ 13), as "flatly inconsistent with the medical literature").[8]

The State's citation to a single digoxin study including women between 17 to 24 weeks LMP, *see* Opp. 23, does not alter the fact that the use of digoxin before 18 weeks LMP would be experimental. As an initial matter, the State does not contest that D&Es are provided starting at 15 weeks LMP, but there are no digoxin studies on women before 17 weeks LMP. Thus, the use of digoxin is undisputedly experimental for a significant portion of women seeking D&Es in Ohio. *See, e.g.*, *West Ala. Women's Ctr. v. Miller*, 217 F. Supp. 3d 1313, 1343 (M.D. Ala. 2016) ("[N]o study has been done on the efficacy, dosage, or safety of injecting digoxin into women before 17 weeks of pregnancy."), *aff'd*, 900 F.3d 1310 (11th Cir. 2017), *petition for cert. filed*, No. 18-837 (U.S. Dec. 20, 2018). Further, the cited study does not state how many study participants were at 17 weeks LMP or what the efficacy and effects were for that gestational age versus later ones. A single study, lacking in specific conclusions about the safety or efficacy of digoxin at 17 weeks, does not establish the safety and efficacy of the procedure for the entirety of the second trimester.

The State's focus on the current use of digoxin at PPSWO and Women's Med also ignores a critical distinction: the Act requires not that physicians merely *attempt* demise but that they *successfully cause* demise in every case.[9] Physicians at these providers use digoxin to

---

[8] Given the smaller volume of amniotic fluid before 18 weeks LMP, digoxin that was injected intra-amniotically would be more concentrated, and it is unknown what effect this higher concentration would have on the woman's absorption of the medication. 2d Keder Decl. ¶ 14. Use of digoxin at early gestational stages also may present greater risks of damaging organs and other structures due to the smaller size of the uterus. *Id.*

[9] The only exception is an extremely narrow one triggered when there is "*serious* risk of *substantial and irreversible* physical impairment of a *major* bodily function." S.B. 145 (emphases added). For reasons explained below, the Act imposes undue burdens long before a patient's health deteriorates to the point of facing irreversible failure of a major bodily function.

attempt demise in a minority of D&E patients (*i.e.*, starting at 18 weeks LMP) to reduce the chance of accidentally violating the federal ban on so-called "partial birth abortions" (D&X) when performing D&E. But the ban on D&X abortions does not penalize doctors who attempt to comply. Thus, should demise fail, the physician can nevertheless safely complete a D&E without fear of violating the D&X ban. By contrast, under the Act, completing the D&E before confirming successful demise would be a felony. Thus, in the up to 10% of cases in which digoxin fails, doctors would either have to violate the Act, compromise patient care by attempting a second and experimental demise procedure, or allow the patient's health to deteriorate until the Act's narrow health exception was triggered. Keder Decl. ¶ 35.[10]

The State also ignores that digoxin injections are not provided at *any* gestational age at PPGOH, where the physicians are not trained to do so. *See* Declaration of Katherine Rivlin, M.D. (Rivlin Decl.) ¶ 17. Dr. Valley claims that PPGOH could simply begin performing digoxin injections, which he characterizes as "an extension of the amniocentesis procedure—a procedure that obstetric practitioners may easily learn during residence." Valley Decl. ¶ 14. But his declaration provides no basis for him to opine on what training OB/GYN residents receive today, as he last taught residents more than 20 years ago. *See id.* ¶ 1. By contrast, Plaintiffs' expert Dr. Keder is currently a professor at the Ohio State University Wexner Medical Center and states

[10] Similarly, the State cites to the existence of an outdated, decade-old document from Planned Parenthood Federation of America requiring digoxin injections for certain procedures beginning at 18 weeks LMP in certain cases as evidence that the demise requirement cannot constitute an undue burden. *See* Opp. 6 (citing Opp. Ex. B-17). But this document, which is no longer in effect, was spurred by the same reasons that PPSWO and Women's Med attempt digoxin—for legal reasons related to the ban on D&X. The document also acknowledges the digoxin failure rate, as well as adverse events from digoxin and from the needle injection. Opp. Ex. B-17 at PAGEID #442. Furthermore, the trend among physicians is away from the use of digoxin; it is currently used by only a minority of physicians nationally, given that 74% of providers do not attempt any fetal demise procedure before D&Es. 2d Keder Decl. ¶ 4.

that amniocentesis is not taught during OB/GYN residency, but rather reserved for Maternal Fetal Medicine (MFM) fellows. 2d Keder Decl. ¶ 25. Further, not all Ohio physicians who perform abortions completed an obstetrics residency. *See, e.g.*, Declaration of Sharon A. Liner, M.D. (Liner Decl.) ¶ 2. For all these reasons, Dr. Valley's unsupported assertion that digoxin injections provide a reliably safe and effective way of performing demise "on *any* fetus in the second trimester" (Valley Decl. ¶ 12) is contradicted by the record evidence and has been rejected by every court to have ruled on the question. *See, e.g.*, *Miller*, 217 F. Supp. 3d at 1342-43 (digoxin injections are "not reliable for inducing fetal demise" given failure rate, are experimental at the time most women receive D&Es, and "carry significant health risks").

Faced with this overwhelming evidence and clear precedent, the State attempts to create "medical uncertainty" about whether "use of digoxin [before 18] weeks LMP . . . will create significant health risks." Opp. 23. This both misstates the facts and is wrong on the law. On the facts, the absence of evidence of health risks is not evidence of patient safety. There is no uncertainty that the use of digoxin before 18 weeks LMP is virtually unstudied and thus the safety and effectiveness is unknown. And as Dr. Keder explains, digoxin injections at earlier gestations would likely be more technically challenging and riskier to surrounding structures due to smaller uterine size. 2d Keder Decl. ¶ 14. Dr. Valley's unsubstantiated statement that digoxin can be performed before 18 weeks LMP "with the same success as when performed in later gestation," Valley Decl. ¶ 12, is unsupported by the medical literature and entirely ignores the patient's safety.

On the law, the State's assertion that legislatures, not courts, must resolve questions of medical uncertainty in facial challenges, Opp. 28, is "inconsistent with th[e Supreme] Court's case law." *Whole Woman's Health*, 136 S. Ct. at 2310. Though the State suggests that *Gonzales*

demands such deference, Opp. 28, the Supreme Court in *Whole Woman's Health* rejected this very argument, pointing out that, in fact, *Gonzales* stated that the "Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake." 136 S. Ct. at 2310 (quoting *Gonzales*, 550 U.S. at 165); *Gonzales*, 550 U.S. at 166 ("[u]ncritical deference to [legislative] factual findings . . . is inappropriate."). In particular, giving significant weight to the court's own factfinding is "consistent with [the Supreme] Court's caselaw" where the statute sets forth no legislative findings, as is the case here. *Whole Woman's Health*, 136 S. Ct. at 2310. Further, the Court's discussion of "medical uncertainty" in *Gonzales* related to its determination that the ban on a little-used procedure should not be invalidated on its face when there was such uncertainty about whether it would threaten women's health. *Gonzales*, 550 U.S. at 150-54, 163-64. Here, there is no such uncertainty as to the use of digoxin before 18 weeks, or as to any of the fetal demise procedures the State advocates, as requiring that fetal demise be accomplished prior to every D&E would expose all patients to increased health risks. Such a law is no doubt unconstitutional. *Stenberg*, 530 U.S. at 937-38; *Danforth*, 428 U.S. at 77-79; *see also Northland Family Planning*, 487 F.3d at 331-32.

b. Potassium chloride injections are not a feasible means of complying with the Act

The State's assertion that potassium chloride (or KCl) injections offer a second, easily available method of demise is unsupported by the evidence, including the State's own cited studies. None of Plaintiffs' physicians provide KCl injections, which are difficult and highly technical procedures that require a doctor to insert a needle through a patient's abdomen, precisely reaching a small moving target. Rebuttal Declaration of Steven J. Ralston, M.D., M.P.H. (Ralston Decl.) ¶ 26; 2d Keder Decl. ¶ 25; *see* Opp. 10 (conceding that KCl injections are complicated and require ultrasound guidance and precision to target fetal structures while

avoiding the woman's circulation). The procedure is difficult regardless of whether the injection is administered in the fetal heart, as is the standard, accepted procedure, or the larger fetal chest space, as Dr. Valley suggests can be easily done.[11] Both target a small moving object and would be unsafe if not performed by MFM specialists who have undergone extensive training. *See, e.g.*, Opp. Ex. B-11 (all KCl injections were performed or supervised by MFM specialists); Opp. Ex. B-10 (same); Keder Decl. ¶ 40; Ralston Decl. ¶¶ 26-27, 30-31. There is no dispute that Plaintiffs' physicians are not MFM specialists and accordingly, *none* of the Plaintiffs offers KCl injections. Rivlin Decl. ¶ 21; Liner Decl. ¶ 22; Haskell Decl. ¶ 19; Opp. 11.

Moreover, the advanced training necessary to perform these procedures competently is not provided to obstetrics residents. Ralston Decl. ¶ 31. Nor is such training available to Ohio clinicians. 2d Keder Decl. ¶ 27 (noting that the procedure is infrequently performed even in specialized settings). Dr. Valley's assertion that such injections are "easily performed" with little risk to a woman by any obstetrics resident with minimal additional training (Valley Decl. ¶ 17) is not credible, unsupported, ignores the fact that not all abortion providers are obstetricians, and contradicts the State's own assertions and every court to have ruled on the

[11] The State's claim that Plaintiffs can perform intrathoracic injections (Opp. 31; Valley Decl. ¶ 17) disregards the fact that intrathoracic injections still require technical expertise and training to precisely reach a small moving target. *See* Ralston Decl. ¶ 42. Compared to intracardiac injections, intrathoracic injections are more time consuming and typically require a higher dose of potentially lethal medication, exposing the patient to even greater risks of complication. *Id.* ¶ 41. Moreover, Dr. Valley's contention that intrathoracic injections are as effective as intracardiac injections is not even supported by the article on which he relies, which makes no findings on the acceptability and efficacy of intrathoracic KCl. Valley Decl. ¶ 17 (citing Singh, et al., *Fetal Intracardiac Potassium Chloride Injection to Expedite Second-Trimester Dilation and Evacuation*, 31 Fetal Diagnosis & Therapy 63-68 (2012)). The Singh article did *not* study intrathoracic injections, but rather reviewed records of 23 patients who had a D&E after successful demise with intracardiac KCl. It accepted placement of injections in the thorax during the early second trimester as eligible for the study but was silent on whether any instances actually occurred. *See* Ralston Decl. ¶ 40.

question.[12] *See, e.g.*, *Whole Woman's Health v. Paxton*, 280 F. Supp. 3d 938, 950 (W.D. Tex. 2017) ("Injecting potassium chloride requires great technical skill and is extremely challenging. The procedure requires extensive training generally available only to subspecialists . . . . The record evidence is, and there is no credible dispute, that the procedure . . . is very rare, as it carries much more severe risks for a woman, including death if the physician places the solution in the wrong place."), *appeal filed*, No. 17-51060 (5th Cir. Dec. 1, 2017); *see also* Opp. 23 (injection into woman's bloodstream can result in "serious complication[]s"). KCl injections, therefore, are not a feasible or safe way for women to access abortions under the Act.

c. Umbilical cord transections are not a feasible means of complying with the Act

The State's claim that umbilical cord transection constitutes a third feasible and safe method of demise is contradicted by its own cited study concluding that the procedure is "far more invasive and bears more risk" than other methods of demise. *See* Opp. Ex. B-04 at PAGEID #352; *see also* Keder Decl. ¶ 44 (explaining that umbilical cord transection carries increased risks of uterine perforation and excessive bleeding, and can lengthen the procedure significantly, undermining its safety).[13] Nor is the State correct that umbilical cord transection is effective and reliable; as Dr. Keder has explained, it is simply not always possible to locate and

---

[12] Dr. Valley's comparison of KCl injection and amniocentesis (Valley Decl. ¶ 14) similarly misses the mark. KCl which must be injected into specific fetal spaces to work, requires a far higher level of skill than amniocentesis, which requires only the much-easier technique of entering the amniotic fluid. Ralston Decl. ¶¶ 29, 42; 2d Keder Decl. ¶ 25; *see also Planned Parenthood of Cent. N.J. v. Farmer*, 220 F.3d 127, 145 (3d Cir. 2000); *Paxton*, 280 F. Supp. 3d at 950. Similarly, that other specialized intrauterine procedures may require greater precision, *see* Valley Decl. ¶ 14, does not change the fact that safe performance of KCl injections requires a high degree of skill from specialized training and repeated practice. Ralston Decl. ¶¶ 26, 32.

[13] The State once again contends that these risks cannot amount to an undue burden because they are the same risks associated with the D&E procedure itself. Opp. 24. As is explained above, *see supra* note 7, this argument has no merit.

transect the cord. Keder Decl. ¶ 43. The State's reliance on the sole published study on this procedure, which has severe limitations, to contend that umbilical cord transection is "nearly always effective," Opp. 11, 24, only underscores that the procedure is essentially experimental.

In any event, cord transection is not a feasible method of demise because any physician who attempts to transect the cord runs a "high and certainly probable risk" of accidentally grasping fetal tissue instead of the umbilical cord—thereby violating the Act's prohibition on separating fetal tissue before demise. 2d Keder Decl. ¶ 29. That risk increases at earlier gestational stages when the cord is small and even more difficult to distinguish from tissue on an ultrasound. *Id.* The State dismisses this concern, contending that accidentally grasping tissue would not amount to a violation of the Act because the physician did not "knowingly" perform a "dismemberment" abortion; that is, they were not aware that their conduct would "*probably* cause a certain result." *See* Opp. 24. All parties agree, however, that a physician *knows* that in attempting to reach for the cord, she may grasp fetal tissue instead of or in addition to the cord. *See id.* The State's interpretation that providers would not be prosecuted under such circumstances is hardly a forgone conclusion given the high risk of inadvertently grasping fetal tissue. *See* 2d Keder Decl. ¶ 29. Nor is such reassurance precedential or binding; the Attorney General could reverse himself whenever he sees fit, as could any future Attorneys General and any of Ohio's 88 county prosecutors. *See Northland Family Planning*, 487 F.3d at 342.

Given these grave concerns, it is unsurprising that every court to consider the issue has rejected cord transection as a feasible means of complying with a similar statute. *See, e.g.*, *Paxton*, 280 F. Supp. 3d at 952 (rejecting cord transection as infeasible based on its "technical difficulties," "potential for serious harm," and "lack of sufficient research"); *Hopkins*, 267 F. Supp. 3d at 1063-64.

C. The State Fails To Establish That Any Benefits The Act Confers Outweigh The Burdens It Creates

The State offers three interests it claims the Act advances that outweigh any burdens: "promoting respect for life, protecting the integrity of the medical profession, and ensuring unborn children do not needlessly suffer pain." Opp. 15. But these interests are the same as those asserted in *Stenberg* and *Gonzales*, which make clear that while such interests may be adequate to support a ban on a rarely used procedure when a safe alternative exists, they do not allow a state to ban the dominant abortion method in the second trimester. *See Stenberg*, 530 U.S. at 925 (acknowledging what the D&E procedure entails but holding that a ban on D&E abortion imposes an undue burden); *Gonzales*, 550 U.S. at 156-57; *Carhart v. Ashcroft*, 331 F. Supp. 2d 805, 1027 (D. Neb. 2004).

Moreover, the factual record belies the State's claim that the Act actually furthers these interests. For example, the State argues that the Act aligns with patients' preferences, Opp. 16, claiming 90% of patients prefer demise prior to an abortion. But the State's reliance on a single study by Jackson, *et al.*, *see* Opp. 6 (citing Opp. Ex. B-03), is misplaced and is highly misleading for reasons explained in the State's own cited studies. As discussed in the Gariepy study cited by the State, preoperative demise was mandated in the Jackson study. *See* Opp. Ex. B-09. When demise was *not* mandated, 81% of women undergoing D&E *declined* digoxin. *Id.* Further, the Jackson study shows that only 35% of the participants listed a desire for fetal death before the procedure as a reason they would choose digoxin, while others indicated they would do so because they were under the "mistaken belief that digoxin is associated with an easier and less painful procedure, which was disproved in this same trial." Opp. Ex. B-09 at PAGEID #386-87. The State's claims about patient preference are simply unsupported.

In support of its assertion that the Act "protect[s] the profession's integrity and ethics," the States claims that D&E without demise is distressing to medical providers and coarsens the profession. Opp. 17. However, the State bases this claim on a nearly 40-year-old article reporting on a survey of only 15 health clinic staff. *See id.*; Valley Decl. ¶ 11. Dr. Valley likewise relies on a nearly 30-year-old article that appeared in the *Los Angeles Times* describing a single physician's experience. Valley Decl. ¶ 11. Dr. Keder, who has extensive and *current* experience performing D&Es in Ohio, has never had clinicians or staff experience mental distress as a result of performing D&Es; to the contrary, these providers have elected to perform D&Es. 2d Keder Decl. ¶ 10. Plaintiffs have also submitted sworn declarations from several physicians who currently perform D&Es in Ohio explaining why the Act would place them in the untenable (and emotionally and ethically difficult) position of choosing between what is best for their patients and avoiding criminal liability. *See, e.g.*, Keder Decl. ¶ 35. Thus, as Dr. Keder explains, it is the Act, not D&E, that violates medical ethics. 2d Keder Decl. ¶ 11.

Finally, the State claims that there is medical uncertainty about the existence of fetal pain during the second trimester, and therefore, the Act eliminates "possible [fetal] pain." *See* Opp. 17. This assertion is simply wrong. Its only evidence is a single study showing that fetuses respond to sensory input. *See* Valley Decl. ¶ 9. But as Dr. Ralston, a board-certified obstetrician-gynecologist, MFM specialist, and fetal pain expert, explains: the clear medical consensus is that a fetus cannot feel pain before at least 24 weeks LMP because experiencing pain requires neural connections that are absent before then, Ralston Decl. ¶ 9, *and* the best medical evidence indicates that even after those pathways develop, "environmental factors inherent to the uterus keep the fetus in a continuous sleep-like state" that "is inconsistent with the ability of a fetus to experience pain" until after birth. *Id.* ¶ 16. Because abortions in Ohio are

performed only up to 21 weeks and 6 days, *see* ECF No. 4 (Pls.' Mem. 5), fetal pain during a D&E in Ohio is an impossibility.

In short, in the face of the concrete and substantial burdens established in the record, the State offers nothing of substance to show that the Act furthers its purported interests. There is no question that, as every other court to address similar laws has found, the burdens the Act imposes on Ohio individuals substantially outweigh any possible benefits.

II. ALL OTHER PRELIMINARY INJUNCTION FACTORS FAVOR THE PLAINTIFFS

Absent an injunction, individuals seeking D&Es in Ohio, including Plaintiffs' patients, will face irreparable, immediate harm. The Act unconstitutionally infringes on individuals' right to choose an abortion, which is itself irreparable harm. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976). Though the State attempts to minimize the harms associated with mandatory fetal demise, Opp. 31-32, the record demonstrates that the State's proposed demise methods are invasive and add risk for patients, are often experimental, do not always work, and are not possible for some patients. In contrast to exposing Plaintiffs' patients to these harms, an injunction would only preserve the status quo, maintaining access to a procedure that has been repeatedly judged constitutionally protected. *See Preterm-Cleveland v. Himes*, 294 F. Supp. 3d 746, 757 (S.D. Ohio 2018).

Finally, the public interest favors an injunction. *See Planned Parenthood Sw. Ohio Region v. Hodges*, 138 F. Supp. 3d 948, 961 (S.D. Ohio 2015); *Doe v. Barron*, 92 F. Supp. 2d 694, 697 (S.D. Ohio 1999). The State argues that the statute promotes the public interest in avoiding fetal pain, Opp. 32, but as explained above, the well-established medical consensus is that second-trimester fetuses lack the neural pathways required to experience pain, Ralston Decl. ¶ 9. Likewise, the State's assertion that the Act serves a public interest in protecting the medical

profession ignores the express concerns of Ohio providers that the statute would place them in the ethically impossible position of choosing between their patients' best interests and avoiding criminal liability. *See, e.g.*, 2d Keder Decl. ¶ 11; Liner Decl. ¶ 26; Rivlin Decl. ¶ 25.

III. PLAINTIFFS ARE ENTITLED TO FACIAL RELIEF

Plaintiffs are entitled to facial relief because the Act imposes an undue burden on a "large fraction" of patients for whom the statute is an actual, rather than an irrelevant, restriction. *See Casey*, 505 U.S. at 894 ("The proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant."). The State's contention that Plaintiffs have failed to show a burden in a "large fraction" of cases misapplies the standard announced in *Casey*, relying on both the wrong numerator and denominator.

The applicable denominator here is all individuals seeking a D&E in Ohio, as these are the people for whom the Act is a relevant restriction. As to the numerator, the State suggests the Act burdens only patients who experience a digoxin failure, Opp. 22, and for whom cord transection is not feasible, *id.* at 24-25. But the State's argument ignores that a physician cannot determine at the outset of each and every D&E whether she will be able to successfully cause demise without jeopardizing the patient's health. *See supra* Section I.B.2 (describing consequences of a failed demise attempt). It also ignores extensive record evidence—including its own cited studies—showing the downsides and shortcomings of digoxin injections, KCl injections, and umbilical cord transections. The Act, therefore, burdens *all* patients seeking a D&E in Ohio by banning the procedure without providing a safe, reliable, and available alternative.

But even if the State were correct that the Act does not burden patients who would receive digoxin anyway (which is incorrect because today physicians can safely complete those procedures if the digoxin fails), the Act still burdens a large fraction of those seeking a D&E in

Ohio, namely: (1) the between 53% and 85% of Plaintiffs' patients (depending on the provider) who obtain a D&E before 18 weeks LMP;[14] (2) all PPGOH patients at and after 18 weeks LMP —approximately 100 per year, Krishen Decl. ¶ 7—since PPGOH does not currently use digoxin or any other demise method at any gestational age; (3) all patients at providers that use digoxin after 18 weeks LMP for whom the digoxin fails, which studies show can be up to 10% of patients; and (4) patients for whom demise procedures are contraindicated or technically infeasible, who could be denied their abortion right entirely. *See* 2d Keder Decl. ¶ 3. This unquestionably constitutes a large fraction of patients seeking D&Es in Ohio, entitling Plaintiffs to a facial preliminary injunction of the Act.

The State suggests that certain limited relief—*i.e.*, an injunction from 15 to 17.6 weeks LMP—would provide adequate protection, Opp. 34, but the narrow injunction proposed by the State would require this Court to "rewrite[e] state law," which the Supreme Court and Sixth Circuit have strongly cautioned against. *Northland Family Planning Clinic, Inc.*, 487 F.3d at 333-34 (states cannot "merely cast as wide a net as possible and leave it to the courts to determine the permissible extent of a statute's reach" (citing and quoting *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 330 (2006)); *see also Stenberg*, 530 U.S. at 944–46 (facially enjoining statute that banned both D&X and D&E abortions, rather than crafting narrow relief enjoining only the D&X ban).

However, if the Court is inclined to grant narrow relief, at least four circumstances would need to be included. *First*, as the State itself seems to admit, the Act should be enjoined as it applies to D&E abortions performed before 18 weeks LMP, as it would be a wholly experimental

[14] In 2018, the percentages of D&Es performed before 18 weeks LMP was as follows: 85% at PPSWO, 2d Liner Decl. ¶ 3; 53% at Women's Med, 2d Haskell Decl. ¶ 3; and 70% at PPGOH, Krishen Decl. ¶ 6.

procedure and contrary to the standard of care. *Second*, the Court should protect physicians who accidentally remove fetal parts when intending to comply with demise requirements. For example, because removal of fetal parts is highly probable when performing umbilical cord transection, *see* 2d Keder Decl. ¶ 29, without an injunction, providers would risk committing a felony each time they attempt a transection. *Third*, the Court should enjoin the Act to the extent it prohibits physicians from completing a D&E procedure after an attempted demise procedure fails. This would protect physicians from having to choose between legal compliance and protecting patient health, as well as avoid exposing patients to additional, untested, demise procedures. *Finally*, to avoid preventing individuals from obtaining abortions, the statute cannot apply to cases where a physician performs a D&E procedure without demise after making a medical determination that a given patient is not a candidate for a demise procedure, either because a procedure is contraindicated or simply impossible for that patient.

But the better course of action, as all other courts faced with similar laws have done, is to preliminarily enjoin the Act in its entirety. *See Whole Woman's Health v. Paxton*, 264 F. Supp. 3d 813 (W.D. Tex. 2017); *Hopkins*, 267 F. Supp. 3d 1024; *W. Alabama Women's Ctr.*, 217 F. Supp. 3d 1313.

CONCLUSION

For these reasons, this Court should grant Plaintiffs' motion for a preliminary injunction and/or a temporary restraining order.

March 16, 2019

Respectfully submitted,

MELISSA COHEN (*pro hac vice*)
PLANNED PARENTHOOD FEDERATION OF AMERICA
123 William Street, Floor 9
New York, NY 10038
(212) 541-7800
(212) 247-6811 (fax)

RICHARD MUNIZ (*pro hac vice*)
PLANNED PARENTHOOD FEDERATION OF AMERICA
1110 Vermont Avenue NW, Suite 300
Washington, DC 20005
(202) 973-4800
(202) 296-3480 (fax)

Counsel for Plaintiffs Planned Parenthood Southwest Ohio Region, Planned Parenthood of Greater Ohio, Sharon Liner, M.D.

JENNIFER L. BRANCH (OHIO BAR. NO. 0038893)
Trial Attorney for Plaintiffs
GERHARDSTEIN & BRANCH CO. LPA
441 Vine Street, Suite 3400
Cincinnati, OH 42502
(513) 621-9100
(513) 345-5543 (fax)

Counsel for Plaintiffs Planned Parenthood Southwest Ohio Region, Planned Parenthood of Greater Ohio, Sharon Liner, M.D., Women's Med Group Professional Corporation

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD (*pro hac vice*)
LAURA BAKST
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

JENNY PELAEZ
WILMER CUTLER PICKERING HALE AND DORR LLP
350 South Grand Avenue, Suite 1200
Los Angeles, CA 90071
(213) 443-5300

ALLYSON SLATER
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

SARA SCHAUMBURG
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Counsel for Plaintiffs Planned Parenthood Southwest Ohio Region, Planned Parenthood of Greater Ohio, Sharon Liner, M.D.

CERTIFICATE OF SERVICE

I, Alan E. Schoenfeld, hereby certify that the foregoing was electronically filed with the U.S. District Court, Southern District of Ohio, on March 16, 2019, and served upon all parties of record via the court's electronic filing system.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD